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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/632,970
Filing Date: August 04, 2003
Appellant(s): PATEL, SATISHCHANDRA P.

Edward E. Meilman
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/13/07 appealing from the Office action mailed 09/19/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 4-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulye WO 00/33862 (Mulye '862).

Mulye teaches a self-emulsifying composition comprising 0.01-50% cyclosporine, nonionic surfactant having HLB greater than 10, and mixture of fatty acids such as propylene glycol ester having at least about 60% by weight monoesters based on the total weight of the propylene glycol ester (abstract; page 14; pages 16, lines 28 through page 17, lines 1-9; and page 20). The composition is suitable for drinking solution, and hard/soft gelatin capsule formulations (page 23, lines 21 through page 24, lines 1-6). The composition further comprises antioxidants such as tocopherol, BHA, BHT, and the like (page 21, lines 20-27).

Mulye does not explicitly teach mixture of mono- and diester propylene glycol. However, Mulye teaches mixture of propylene glycol maybe use. Thus, it would have been obvious to one of ordinary skill in the art to include diester propylene glycol in the mixture, because Mulye does not exclude the use of diester propylene glycol, because

Mulye teaches mixture of fatty acids contain 60% of monoester propylene glycol (page 16), and because Mulye only exclude the present of triglycerides.

(10) Response to Argument

Appellant argues that the composition of the present invention differs from Mulye in two respects, namely that the fatty acid has from 8 to 10 carbon atoms rather than 6 to 18, and that the monoester is less than 60 mole percent of the monoester/diester mixture. In an Advisory Action, the Examiner observed that "about" 60 wt% could encompass 58-59%. However, this observation fails to take into account that by virtue of the presence of the second ester moiety, the diester is heavier than the monoester, and therefore, 60 mole percent will be substantially less than 60% monoester on a weight basis. A 60 mole % content of the propylene glycol monoester of the C_8 fatty acid in a mixture with propylene glycol C_8 fatty acid diester corresponds to 48 weight percent; and the corresponding conversions into weight percents for the C_9 and C_{10} fatty acid monoesters are lower than for the C_8 fatty acid. Thus, Mulye requires at least "about" 60 wt% monoester (or 58% and higher according to the Examiner) while the invention uses less than 50 wt%.

However, in response to appellant argument that Mulye teaches fatty acid has from 6 to 18 carbon atoms rather than 8-10 carbon atoms, appellant's attention is called to page 15, lines 29-30, where Mulye teaches propylene glycol ester preferably contains 8-10 carbon atoms. In response to applicant's argument that Mulye fails to show certain feature of applicant's invention, it is noted that the feature upon which applicant relies (i.e., less than 50% monoester) is not recited in the rejected claims. Although the

claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The present claims require monoester of between 50% and 60%. Accordingly, the "at least about 60%" taught in Mulye falls within the claimed range.

Appellant argues that Mulye's Comparative Examples 1 and 2 demonstrate that formulations with monoester of 45-50% precipitated and crystallized after 1 week or 2 weeks. Accordingly, Mulye teaches that the composition must contain more than about 60% monoester in order to be storage stable and non-hydroscopic, and thus teaches the skilled person that a composition in which the monoester is less than about 60% by weight will not be storage stable and will be hydroscopic.

However, in response to appellant's arguments, it is noted that the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Mulye cannot be limited to his best mode invention by the disclosure in the examples. The comparative examples 1 and 2 only show monoester of 45-50% will precipitate and crystallize. However, the examples do not show any comparative data of monoester content between 50%-60%. Meanwhile, Mulye suggests monoester of at least about 60%, which could include anything from 55%. Moreover, it would have been obvious to one of ordinary skill in the art to, by routine experimentation modify the amount of monoester to optimize the solubilization

parameters of the cyclosporins in various carrier medium to obtain the claimed invention. This is because the monoester makeup is used for solubilization, because Mulye teaches formulations with extensive advantageous results disclosed in pages 26-28, and because differences in concentration *will not* support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is *critical*. When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Appellant argues that the prior art teaches the critical minimum amount of the monoester value is 60 wt% and the optimum is about 90%. Determination that an amount of less than 50% is better if the fatty acid has 8 to 10 carbon atoms is clearly unexpected and not predicable. The Applicant surprisingly discovered that when the fatty acid was an 8 to 10 carbon atoms and also when the monoester was less than 50 weight percent rather than greater than about 60% by weight, the composition was storage stable. This result is demonstrated in the working examples and also verified and discussed in the Rule 132 Declaration. The Declaration points out in paragraph 3 that two compositions which differed only in the monoester content gave very different results when tested under the same conditions. At 10 wt% monoester, there was crystallization and precipitation after I week whereas at between 50 and 60 mole percent, the solution remained clear for at least 4 weeks. It also points out that when the fatty acid carbon content was increased to 12 carbon atoms (Comparative Example 2),

the solution was unstable at 4 weeks storage as indicated by being hazy. These results are, as stated, surprising, unexpected, and unpredictable.

However, while the parameters between Mulye and the present invention might not be the same, they are either within the claimed range, or close to the range. Mulye teaches propylene glycol ester contains 8-10 carbon atoms (column 15, lines 29-30), which falls within the claimed range of 8-10 carbon atoms. The only different in Mulye is the monoester content of at least about 60% while the present claims require between 50-60%. However, as stated above, differences in concentration *will not* support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is *critical*. When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The Declaration under 37 CFR 1.132 filed 09/11/07 is insufficient to overcome the rejection by Mulye because Mulye teaches formulations with extensive advantageous results such as (see pages 26-28). The examples of Mulye show formulations that stayed clear (stable) even after *more than three months*.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/S. Tran/, Primary Examiner Art Unit 1618

Conferees: /Michael G. Hartley/ Supervisory Patent Examiner, Art Unit 1618

/SREENI PADMANABHAN/

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